



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*Given to Vic Don
6/24/93*

MAY 25 1993

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Registration No. 8340-UI; Arise Grass and Weed Killer; Response To Hoechst-Roussel Agri-Vet Co.'s Memo (Victor Dorr to Joanne Miller; 4-28-93).

To: Joanne I. Miller (PM 23)
Attn: Jesse Mayes
Herbicide & Fungicide Br. (HFB)
Registration Division (H7505C)

From: Thomas C. Ellwanger, Jr. *Thomas C. Ellwanger, Jr.*
Head, Precautionary Review Section
Registration Support Br. (H7505W)

Request (HFB)

Respond to the comments in: Letter (Victor Dorr to Joanne Miller; 4-28-93).

Response (PRS):

Discussion

The sensitization study (MRID 423168-19) reviewed by the PRS remains classified as supplementary. The irritation screening used only test concentrations of 50% or less. With the limited irritation screening (50% or less), we do not know if the proper concentration was selected for the sensitization study. Would a concentration greater than 50% be a sensitizer?

We have trouble translating the scores assigned for the study (MRID 423168-19). The scoring system used was the one for the §81-5 dermal irritation tests [0 = no erythema; 1 = very slight (barely perceptible); 2 = well defined; 3 = moderate to severe erythema; 4 = severe erythema (beet redness to slight eschar (injury in depth)]. We recommend using the scoring system devised by the author of the sensitization technique. [0 = no reaction; 0.5 = very faint erythema, usually confluent; 1 = faint erythema, usually confluent; 2 = moderate erythema; 3 = strong erythema with or without edema].

We cannot comment on the products sold in other countries, because we do not know the confidential statements of formula nor have we reviewed the guinea pig dermal sensitization studies if required. In addition, several questions arise pertaining to no reported human sensitization for the products sold in other countries and would include the following: 1) How accurate is their reporting system for receiving, tracking, and depicting all human sensitization reactions to these products? 2) What are the chances of incidences not being reported?

PRS does, however, accept the argument that the dermal sensitization study supporting 8340-UA/UE can also support 8340-UI. This is due to the fact that each ingredient in -UI (with the exception of water) is either present in lesser quantities or absent when compared to 8340-UA/UE.

Recommendation: A sensitization study conducted on 8340-UI is not required since an existing study on 8340-UA/UE can be cited. The sensitization study on 8340-UA/UE was reviewed by HED and not rereviewed by PRS. 8340-UI can be considered a nonsensitizer on this basis.